



Activity Report Implementation Guidelines for REMS CE Data Exchange

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0.1	June 14, 2018		Initial draft
0.2	August 28, 2018	Valerie Smothers	Added veterinarian to professions list; corrected value of time in practice (0-5 years post training). Updated link to definitions, p 14.
0.3	January 28, 2019	Valerie Smothers	Changed addiction to Substance Use Disorder. Corrected TimeInPractice value to include 0-5 years post training instead of >5 years post training. Indicated the following are optional for learners: StateOfPrimaryPractice, DEARegistration, PracticeArea, SurgicalProcedures, TimeInPractice
0.4	May 21, 2019	Anne Farmakidis	Revised the URL in 3.3.1 and 3.3.2 to point to all opioid REMS

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2 Overview

As the Institute of Medicine and others call for reforms to Continuing Medical Education and other types of Continuing Education (CE) for the health professions, there has been an increasing focus on measuring the quality of CE activities. Educators, Accreditors, CE supporters, and government agencies often collect aggregate data on the reach and efficacy of CE activities in order to gauge improvement.

The MedBiquitous Activity Report has been modified to support the compilation of data in support of Food and Drug Administration (FDA) Opioid Risk Evaluation and Mitigation Strategies, or Opioid REMS. The REMS program mandates manufacturers to make “REMS-compliant training” available to Health Care Providers (HCPs) who prescribe opioid analgesics, and FDA, the Accreditors and RPC have agreed that accredited continuing education can fulfill this requirement of the REMS. Since companies regulated by the FDA are required to collect educational outcomes data, demographics, and other metrics related to the reach and impact of the activity, and since it is anticipated that there will be multiple bodies reporting data, a standardized way of collecting/reporting this information is needed. The FDA has requested that educators provide learner level data for analysis.

The Activity Report standard provides a data structure that allows for the exchange of REMS CE-related data. This Implementation Guideline provides general guidance for those organizations implementing Activity Report in support of Opioid REMS CE data collection or dissemination.

The Activity Report standard allows for the exchange of identified CE and certification-related data. Such use of Activity Report is entirely valid and conformant with the standard, but it is not the topic of this implementation guideline.

3 General Guidelines

The following types of data are required for Opioid REMS CE data.

- Reporting information
- Activity information
- Regulatory information
- Participant information

Accredited providers should send data current through Feb 28 to accreditors by March 31.

Accreditors send data to Polaris/RPC by May 9. Accreditors may choose to submit data to the RPC earlier at their sole discretion.

More information on each type of data follows.

3.1 Reporting Information

When communicating data on a CE activity, it's important to note the period for which you are reporting data. Use the following sub-elements of the ActivityReports element to identify the first and last day of the period for which you are reporting data.

- ReportingStartDate
- ReportingEndDate

In addition, indicate the date and time this report was created in the DateTimeCreated element using the XML date time format. A valid value would be 2018-01-23T09:00:00, which indicates January 23, 2018, 9 AM.

Example:

TBD

Also indicate the name of the organization that is the source of the activity report using the ReportingOrganization element.

Example:

TBD

3.2 Activity Information

Activity Report allows for the exchange of detailed information about one or more activities offered by the CE provider. These are under the Activity element of Activity Report. REMS CE requires the following data points.

3.2.1 Provider Organization

The entity serving as the accredited provider for this activity. Accredited provider is conveyed using the ProviderOrganization element of Activity Report.

See the example at the end of this section for more details.

3.2.2 Activity Name

The title of the CE activity. The title is conveyed using the ActivityName element of Activity Report.

See the example at the end of this section for more details.

3.2.3 Commercial Supporter

The commercial organization providing support for this activity. In some cases, the REMS Program Companies provide commercial support for REMS CE. Use the CommercialSupporter element under Activity to indicate the organization providing commercial support for the activity.

See the example at the end of this section for more details.

3.2.4 Module Name

Activity Report requires that a module name be specified for an activity. Most activities have one module, and the module name is same as the activity name. If your activity has multiple modules, you can represent that by repeating the module element and specifying the module name for each module.

3.2.5 Accrediting Body

The organization that sets the quality standards for continuing education and is the source of the accreditation process for this activity. The following values are recommended for REMS CE: AAFP, ACCME, ACPE, ADA, ANCC, AOA, APA, ARBO.

The accrediting body is conveyed using the accreditingBody element of Healthcare LOM [[Healthcare LOM](#)]. Healthcare LOM data can be included under the Metadata element in Module. See the example at the end of this section for more details.

3.2.6 Activity Identifier

An identifier for the activity provided by the CE provider must be included in the data set. The Activity Identifier provided by the CE provider will help to eliminate double-counting of data for activities offered for multiple types of credit.

In addition, an identifier for the activity provided by the RPC or by the accreditor may be included in the data set.

The Activity Identifier is conveyed using the identifier element of Healthcare LOM [[Healthcare LOM](#)]. Healthcare LOM data can be included under the Metadata element in Module. Repeat the identifier element to include multiple identifiers for an activity. For example, some instances may include the identifier generated by the provider as well as the identifier generated by the RPC.

See the example at the end of this section for more details.

3.2.7 Activity Location

The geographical location in which an in person activity takes place. Activity location is conveyed using the activityLocation element in Healthcare LOM [[Healthcare LOM](#)]. Healthcare LOM data can be included under the Metadata element in Module. If an activity is not face-to-face, the activity location element should not be used.

MedBiquitous recommends using the following subelements of activityLocation:

- City
- StateOrProvince
- Country

Note that Country has two subelements: CountryName and CountryCode. For REMS CE, use CountryCode element with the ISO 3166 three-letter alpha code (i.e. USA). See ANSI /MEDBIQ PP.10.1-2008 Address Specifications and Description Document [[Address](#)] and the example at the end of this section for more details.

3.2.8 Activity Date

Use the startDateTime element of Healthcare LOM to indicate the date and time that a live activity begins [[Healthcare LOM](#)]. Healthcare LOM data can be included under the Metadata element in Module. startDateTime uses the dateTime format. For example, 2013-01-31T09:00:00.

3.2.9 Activity type

The type of learning activity described. Activity Type is conveyed using the activityFormat element of Healthcare LOM [[Healthcare LOM](#)]. Healthcare LOM data can be included under the Metadata element in Module.

See the example at the end of this section for more details.

3.3 Regulatory Information

When reporting on REMS CE activities, it is important to identify the specific REMS to which the data relates and indicate whether or not the activity is compliant to all of the requirements set out for CE activities by the regulation. If an activity meets all of the requirements for CE activities set out in the REMS, see the section Compliant Activities.

If the activity meets some but not all requirements set out for CE activities by the REMS (for example, it addresses some but not all elements of the REMS blueprint), see the section Related Activities.

3.3.1 Compliant Activities

Use the CompliantToRegulation element to indicate that the activity described is compliant to requirements outlined in the REMS regulation. The value of CompliantToRegulation is the URI of the regulation. For ER/LA REMS, use the URI for the specific version of the REMS you are supporting. For example: http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/OpioidREMJuly2012.pdf

CompliantToRegulation has the following attribute:

label

A label for the regulation. For example, Opioid REMS.

An example of regulatory information for an activity compliant with the Opioid REMS requirements follows:

```
<RegulatoryInformation>
  <CompliantToRegulation label="Opioid REMS">
https://www.accessdata.fda.gov/drugsatfda\_docs/rems/Opioid\_Analgesic\_2018\_09\_18\_REMS\_Document.pdf
  </CompliantToRegulation>
</RegulatoryInformation>
```

3.3.2 Related Activities

Indicate the activity is related to the REMS

Use the RelatedToRegulation element to indicate that the activity is related to the REMS regulation but does not meet all requirements set out for CE activities by the REMS regulation (for example, it addresses some but not all elements of the REMS blueprint). The value of RelatedToRegulation element is the URI of the regulation. For ER/LA REMS, use the URI for the specific version of the REMS you are supporting. For example:

https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_Analgesic_2018_09_18_REMS_Document.pdf

RelatedToRegulation has the following attribute:

label

A label for the regulation. For example, Opioid REMS.

Indicate which sections of the blueprint are addressed by instruction and assessment

Use the RegulatoryClassification element and its subelements to indicate which REMS blueprint components (sections or elements) are addressed and how they are addressed. You should indicate which section(s) of the blue print are addressed by the instruction and/or assessment if the activity being reported is related to the regulation but not compliant to the regulation.

Use the subelements of RegulatoryClassification to specify each section addressed in the instruction and each section addressed in the assessment.

RegulatoryClassification has the following subelements:

- **ClassificationRelation** – either Assessment Addresses and Instruction Addresses

- **Regulation** – the URI of the regulation. For example, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_Analgesic_2018_09_18_REMS_Document.pdf. Regulation has a label attribute which should have the value Opioid REMS.
- **ComponentID** – The identifier for the blueprint section. For example, II.
- **ComponentTitle** – The title for the blueprint section. For example, Assessing Patients in Pain.

```

<RegulatoryInformation>
  <RelatedToRegulation label=" Opioid REMS">
https://www.accessdata.fda.gov/drugsatfda\_docs/rems/Opioid\_Analgesic\_2018\_09\_18\_REMS\_Document.pdf
  </RelatedToRegulation>
  <RegulatoryClassification>
    <ClassificationRelation>
      Instruction Addresses
    </ClassificationRelation>
    <Regulation label="Opioid REMS">
https://www.accessdata.fda.gov/drugsatfda\_docs/rems/Opioid\_Analgesic\_2018\_09\_18\_REMS\_Document.pdf
    </Regulation>
    <ComponentID>III</ComponentID>
    <ComponentTitle>
      Assessing Patients in Pain
    </ComponentTitle>
  </RegulatoryClassification>
  <RegulatoryClassification>
    <ClassificationRelation>
      Assessment Addresses
    </ClassificationRelation>
    <Regulation label="Opioid REMS">
https://www.accessdata.fda.gov/drugsatfda\_docs/rems/Opioid\_Analgesic\_2018\_09\_18\_REMS\_Document.pdf
    </Regulation>
    <ComponentID>II</ComponentID>
    <ComponentTitle>
      Assessing Patients in Pain
    </ComponentTitle>
  </RegulatoryClassification>
</RegulatoryInformation>

```

3.4 Participant Information

Providers must report demographic information on individual participants of REMS CE. The FDA mandates the collection of the following information on individual learners:

- State of primary practice
- Whether the individual is registered with the DEA to prescribe controlled substances
- Whether the individual is authorized to prescribe controlled substances under an institutional (hospital/clinic) DEA registration

- Profession
- Practice area
- Whether or not the learner performs surgical procedures
- Length of time in practice

Note that the following are optional for learners, but CE providers must make an effort to collect these fields: State Of Primary Practice, DEA Registration, Practice Area, Surgical Procedures, Time In Practice.

The FDA has developed a vocabularies for profession and practice area, as well as options for describing ranges of time in practice.

To avoid confusion, use the following guidelines for developing survey questions related to practice type data allow or instruct participants to choose the single profession and single practice area that best describes them (one response only per question).

Appendix 1 provides sample survey questions.

For Opioid REMS CE, use the definitions posted on the MedBiquitous website at:

https://medbiq.org/opioid_rems_definitions

MedBiquitous recommends collecting learner demographic data at the beginning of a CE activity or during the registration process. Use one participant element per reported participant. The table below describes how to use each element describing participant demographics.

3.4.1 Local Identifier

Use the LocalIdentifier element to include a local identifier for the learner. This should be something that the CE provider can use to determine the individual's identity for auditing purposes, but other organizations should not be able to identify the learner from this identifier.

The LocalIdentifier has a required domain attribute that tells you what kind of ID is being provided. Each CE provider ion may have many ids for its learners, so identifying the type of id within the provider is important. The domain uses the following format:

idd:domainname:localidentifier

Where:

domainname is an internet domain name owned by the CE provider, and

localidentifer is a local identifier for the type of unique ID.

For example, the following would point to a local identifier managed by Boston University's CE department.

idd:bu.edu:ce

3.4.2 State of Primary Practice

Use the StateOfPrimaryPractice element to indicate the state of primary practice for the participant. Do not use abbreviations. Each participant should only be able to select one state of primary practice.

3.4.3 DEA Registration

Use the DEARegistration element to indicate whether or not the participant is able to prescribe controlled substances, and if so, through what mechanism. There are three possible values: Individual, Institutional, and None. Each is described in the table below. The participant should only choose one value.

Individual	Indicates that the participant has an institutional DEA registration
Institutional	Indicates that the participant is able to prescribe through an institutional DEA registration
None	Indicates that the participant is not able to prescribe controlled substances

3.4.4 Profession

Use Profession to indicate the participant's profession. Participants should choose a single profession from the list below:

- Physician
- Advanced practice nurse
- Physician Assistant
- Dentist
- Podiatrist
- Nurse
- Pharmacist
- Optometrist
- Psychologist
- Veterinarian
- Other health care professional
- Other

It is not necessary to provide a space for participants indicating Other health care professional or Other to respond in free text.

3.4.5 Practice Area

Use the element PracticeArea to indicate the clinical area in which the participant practices. The participant should choose one value from the list below.

- Anesthesiology

- Critical Care
- Dentistry
- Emergency
- Family Medicine
- Geriatric
- Hematology
- Hospice and/or Palliative Care
- Internal Medicine
- Neurology
- Obstetrics/Gynecology
- Oncology
- Ophthalmology
- Pain
- Pediatric
- Physical Medicine and Rehabilitation
- Psychiatry
- General surgery
- Orthopedic surgery
- Other surgical specialty
- Substance Use Disorder
- Urology
- Other
- N/A

It is not necessary to provide a space for participants indicating Other health care professional or Other to respond in free text.

3.4.6 Surgical Procedures

Use the SurgicalProcedures element to indicate if the participant performs surgical procedures. If they do perform surgical procedures, use the value True. If they do not, use the value False.

3.4.7 Time in practice

Use the TimeInPractice element to indicate the range that matches the participants time in practice. The participant should choose one value from the list below.

- Trainee (e.g., student, intern, resident, fellow)
- 0-5 years post training
- 6-10 years
- 11-15 years
- 16-20 years
- 21+ years

3.5 What constitutes an activity?

Providers must follow their accreditation body's guidelines regarding what constitutes an activity. For ACCME definitions of different activity types, see: <http://www.accme.org/ask-accme/what-kind-cme-activity-types-can-be-reported-pars>

3.6 Different formats of data exchange (paper, CSV, XML)

Different format may be used to send data to accreditors. Please check with your accreditor to see whether paper, Comma Separated Value (CSV – typically used for exchanging spreadsheets), or XML is acceptable for data exchange. There may be Excel templates or other templates available to facilitate the process of formatting your data.

4 References

Address

ANSI /MEDBIQ PP.10.1-2008 Address Specifications and Description Document. MedBiquitous Website. http://www.medbiq.org/working_groups/professional_profile/AddressSpecification.pdf. Published June 27, 2008.

Healthcare LOM

ANSI/MEDBIQ LO.10.1-2008, Healthcare Learning Object Metadata (Healthcare LOM). MedBiquitous Website. http://www.medbiq.org/std_specs/standards/index.html#HCLOM. Accessed June 1, 2011.

5 Appendix: Sample Survey Questions

The following sample survey questions have been included as examples of questions that may be used to collect REMS-specific demographic data.

(Do we have a volunteer to provide these? the FDA example questions aren't all phrased as questions.)